K041500

JUN 2 1 2004

INFINITT

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
April 28, 2004

Submitter's Information: 21 CFR 807.92(a)(1)

Mr. Samuel Choi, Director
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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	STARPACS ™ Orthopedics System
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050
Name:	System, Image Processing

Predicate Device: 21 CFR 807. 92(a)(3)

Device Classification Name	system, image processing, radiological
510(k) Number	K031590
Regulation Number	892.2050 Class II
Device Name	Sectra orthopedic package
Applicant	sectra-imtec ab
Product Code	LLZ
Decision Date	10/02/2003
Decision	Substantially equivalent (SE)
Classification Advisory Committee	Radiology
Review Advisory Committee	Radiology
Type	Traditional

Device Description: 21 CFR 807 92(a)(4)

STARPACS ™ Orthopedics System handles and displays various objects in a Picture Archive and Communication System (PACS) environment and is intended to assist orthopedic surgeons when doing preoperative planning and post-operative follow-up. The device is used to overlaying prosthesis templates on radiological images, tools for repositioning the templates, and tools for measurements in the images.

Indications for Use: 21 CFR 807 92(a)(5)

The device is intended for the manipulation and displaying of medical images. It can show images from different modalities and interfaces to various image storage and printing devices using DICOM or similar interface standards.

The device assists orthopedic surgeons when doing preoperative planning and post-operative follow-up. Typical users of this system are trained professionals, for example orthopedic surgeons, physicians, and radiologists.

Technological Characteristics: 21 CFR 807 92(a)(6)

STARPACS Orthopedics™ system is a software product that assists orthopedic surgeons when doing preoperative planning and post-operative follow-up. It is a module that is used for displaying and working with prosthesis templates on images that are handled and displayed by the STARPACS™ System (K031013) Workstation. STARPACS ™ Orthopedics System runs on Windows 2000 or Windows XP operating systems, (depending upon system configuration). The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for STARPACS Orthopedics™ system contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

STARPACS Orthopedics™ system has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the "Level of Concern for potential hazards have been classified as "minor".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 1 2004

Infinitt Co., Ltd.
% Mr. N. E. Devine, Jr.
Responsible Third Party Official
Entela, Inc.
3033 Madison Ave. SE
GRAND RAPIDS MI 49548

Re: K041500
Trade/Device Name: STARPACS Orthopedics™ System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: June 4, 2004
Received: June 7, 2004

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: STARPACS Orthopedics™

Indications For Use:

The device is intended for the manipulation and displaying of medical images. It can show images from different modalities and interfaces to various image storage and printing devices using DICOM or similar interface standards.

The device assists orthopedic surgeons when doing preoperative planning and post-operative follow-up.

Typical users of this system are trained professionals, for example orthopedic surgeons, physicians, and radiologists.

Prescription Use __1__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041500